Expéditeur : le BUREAU INTERNATIONAL

# PCT

NOTIFICATION DE TRANSMISSION DE COPIES DE LA TRADUCTION DU RAPPORT D'EXAMEN PRELIMINAIRE INTERNATIONAL SUR LA BREVETABILITE (CHAPITRE I OU CHAPITRE II DU TRAITE DE COOPERATION EN MATIERE DE BREVETS)

(règles 44*bis*.3.c) et 72.2 du PCT)

Destinataire :

GROSSET-FOURNIER, Catherine
Cabinet Grosset-Fournier & Demachy
54, rue Saint-Lazare
F-75009 Paris
FRANCE

| | |
|---|---|
| Date d'expédition *(jour/mois/année)*<br>11 mai 2006 (11.05.2006) | |
| Référence du dossier du déposant ou du mandataire<br>VB/DT/ADENOVIR | **NOTIFICATION IMPORTANTE** |
| Demande internationale n°<br>PCT/FR2004/050214 | Date du dépôt international *(jour/mois/année)*<br>04 juin 2004 (04.06.2004) |
| Déposant<br>TRANSGENE SA etc | |



1. **Transmission de la traduction au déposant.**

☑ Le Bureau international transmet ci-joint copie de la traduction en langue anglaise du rapport préliminaire international sur la brevetabilité (chapitre I).

☐ Le Bureau international transmet ci-joint copie de la traduction en langue anglaise du rapport préliminaire international sur la brevetabilité (chapitre II).

2. **Transmission d'une copie de la traduction aux offices désignés ou élus.**

Le Bureau international notifie au déposant qu'une copie de cette traduction a été transmise aux offices désignés ou élus suivants qui exigent la traduction en question:

Aucun

Les offices désignés ou élus suivants ayant renoncé à l'exigence selon laquelle la transmission doit être effectuée à cette date recevront une copie de cette traduction du Bureau international seulement à leur demande:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Rappel concernant la traduction dans la ou l'une des langues officielles de l'office ou des offices élus.**

Il est rappelé au déposant que, lorsqu'une traduction de la demande internationale doit être remise à un office élu, cette traduction doit comporter la traduction de toute annexe du rapport préliminaire international sur la brevetabilité (chapitre II).

**Il appartient au déposant d'établir la traduction en question et de la remettre directement à chaque office élu intéressé dans le délai applicable (règle 74.1). Voir le volume II du *Guide du déposant du PCT* pour de plus amples renseignements.**

Bureau international de l'OMPI
34, chemin des Colombettes
1211 Genève 20, Suisse

n° de télécopieur+41 22 740 14 35

Fonctionnaire autorisé
Beate Giffo-Schmitt

n° de télécopieur+41 22 338 87 20

# PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Applicant's or agent's file reference<br>**ADENOVIR** | Date of mailing *(day/month/year)*<br>**FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/FR2004/050214 | 04.06.2004 | 05.06.2003 |

International Patent Classification (IPC) or both national classification and IPC

Applicant
**BIOMERIEUX**

1. This opinion contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|---|---|
| Name and mailing address of the ISA/EP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FR2004/050214

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ in written format

☒ in computer readable form

c. time of filing/furnishing

☒ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FR2004/050214

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 5, 7, 8, 10, 16 | YES |
| | Claims | 1-4, 6, 9, 11-15, 17 | NO |
| Inventive step (IS) | Claims | 8, 10 | YES |
| | Claims | 1-7, 9, 11-17 | NO |
| Industrial applicability (IA) | Claims | 1-17 | YES |
| | Claims | - | NO |

2. Citations and explanations:

Reference is made to the following documents:

D1: PANCHOLI PREETI ET AL: "DNA immunization with hepatitis C virus (HCV) polycistronic genes or immunization by HCV DNA priming-recombinant canarypox virus boosting induces immune responses and protection from recombinant HCV-vaccinia virus infection in HLA-A2.1-transgenic mice." JOURNAL OF VIROLOGY, vol. 77, No. 1, January 2003 (2003-01), pages 382-390

D2: WO 01/30812 A (CHIRON CORP; PALIARD XAVIER (US); SELBY MARK (US); HOUGHTON MICHAEL () 3 May 2001 (2001-05-03)

D3: CHO J H ET AL: "Enhanced cellular immunity to hepatitis C virus nonstructural proteins by codelivery of granulocyte macrophage-colony stimulating factor gene in intramuscular DNA immunization" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 17, No. 9-10, 5 March 1999 (1999-03-05), pages 1136-1144

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**NOVELTY** (PCT Article 33(2))

**1.1)** D1 discloses a eukaryotic expression vector (pRS) and a poxviral vector, **comprising** a nucleotide sequence coding for the NS3/NS4 polyprotein and a polynucleotide sequence coding for the NS5b polypeptide of HCV genotype 1b (D1, page 383). Said vectors induce a specific T lymphocyte response, after prophylactic immunization of mice (D1, table 1).
The vectors comprising polynucleotide sequences coding for NS3/NS4 and NS5b are considered to be a kit, because they are used together in the first inoculations ("prime-boost") in the mice (D1, figures 6 and 7).
The subject matter of claims 4, 6, 9, 11-15 and 17 is thus not novel (PCT Article 33(2))

**1.2)** D2 discloses peptide compositions **comprising** NS3, NS4 and NS5 polyproteins and polypeptides of HCV genotype 1b or of HCV of various genotypes, in all the possible combinations (D2, page 14, line 8-page 15, line 12), for inducing a specific T lymphocyte response.
The subject matter of claims 1-3 and 12-14 is thus not novel (PCT Article 33(2)).

**1.3)** The subject matter of claims 5, 7, 8, 10 and 16 is novel (PCT Article 33(2)).

**INVENTIVE STEP** (PCT Article 33(3))

**2.1)** Dependent claims 5, 7 and 16 do not contain any feature which, in combination with the feature of any one of claims to which they refer, meet the requirement of the PCT in respect of inventive step, the reasons being as follows:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

In D2, it is suggested to use adenovirus vectors for expressing HCV polyproteins and polypeptides of various genotypes (D2, page 21, lines 7-14).
D1 discloses a system of two different vaccinal vectors ("prime-boost"), and changing one of the vectors for an adenovirus vector is not the product of an inventive step (PCT Article 33(3)).

**2.2)** Document D3, which is considered to be the prior art closest to the subject matter of claims 8 and 10, describes vectors comprising polynucleotide sequences coding for the **NS3NS4aNS4bNS5aNS5b** polyprotein of HCV (D3, page 1137) for HCV vaccine purposes (D3, tables 1 and 2, figure 2)

The subject matter of claims 8 and 10 differs from these known vectors only by virtue of the presence of the polynucleotide sequences coding respectively for the **NS3NS4aNS4b** polyprotein and the **NS5b** polypeptide in a vaccine vector against HCV, in the absence of any polynucleotide sequence coding for NS5a.

The problem that the present invention is intended to solve can thus be considered to be that of the provision of alternative vaccine vectors against HCV.

The solution, as proposed in claims 8 and 10 of the present application, is considered to be inventive (PCT Article 33(3)) because the prior art does not disclose the fact that a vector containing only polynucleotide sequences coding for the NS3/NS4 polyprotein and the NS5b polypeptide of HCV will induce protection against HCV

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FR2004/050214

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

3) It appears that the word "NS5b" is missing at the end of claim 13.